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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,358	07/03/2003	Don Tanaka	CRD1064NP	7253
27777	7590	05/18/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,358	TANAKA, DON	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. **Claims 1-2**, drawn to a long term oxygen therapy system, classified in class 128, subclass 200.24.
 - II. **Claims 3-4**, drawn to a process for treating hypoxemic patients having chronic obstructive pulmonary disease, classified in class 128, subclass 898.
2. The inventions are distinct, each from the other because of the following reasons: Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process, such as one that does not require supplying oxygen directly into alveolar tissue of a lung.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Carl J. Evens on April 30, 2004, a provisional election was made without traverse to prosecute the invention of I, **claims 1-2**. Affirmation of this election must be made by applicant in replying to this Office action.

5. **Claims 3-4** are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. **Claims 1-2** are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Additionally, the disclosed invention is inoperative and therefore lacks utility. Specifically, the Examiner believes the apparatus cannot function as claimed because in order for the conduit to pass through the thoracic wall and lung of a patient, the conduit must puncture the lung of the patient. Trauma and internal bleeding are a direct result of puncturing the lung. Any action, which punctures the lung, causes negative pressure to affect the lung and as a result, causes fluid to build up and deflate the lung. Without a more detailed explanation of the novelty and utility of this invention, the Examiner does not believe that it is possible to puncture the lung and at the same time, supply oxygen to the inner volume of the lung.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs (US 3,682,166). As shown in Figure 5, Jacobs discloses an apparatus for oxygen therapy with an oxygen supply **15**, a conduit **3** and a sealing device [adhesive tape] (column 3, lines 3-15).

11. Regarding the claimed elements of the conduit, Applicant is reminded that functional language does not hold patentable weight in apparatus claims. Specifically, Applicant states, "at least one conduit having...a second end *passing through the thoracic wall and lung of a patient*," which is method-step terminology, and as a result, has not been given patentable weight in these apparatus claims. The device of Jacobs is *capable of* performing the function as claimed, thus meeting the claim limitation of "*passing through the thoracic wall and lung of a patient*."

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs (US 3,682,166) in view of DeLuccia, deceased et al. (US 4,502,482). Jacobs discloses an oxygen supply apparatus comprising all the limitations recited in **claim 2**, with the exception of a second conduit having multiple branches. However, the use of a conduit with multiple branches was known at the time the invention was made. Specifically, DeLuccia, deceased et al. teaches the use of a second conduit **59** with two branches **63, 67** for establishing fluid communication between different locations inside of patient, as shown in Figure 7. Regarding particular elements of the conduit, Applicant is reminded that functional language does not hold patentable weight in apparatus claims. Specifically, Applicant states, "at least one second conduit having...a second end having multiple branches, one of the branches *passing through the thoracic wall and lung of a patient...*and another of the branches *passing through a bronchus of a patient,*" which is method-step terminology, and as a result, has not been given patentable weight in these apparatus claims. The device of DeLuccia, deceased et al. is *capable of* performing the function as claimed, thus meeting the claim limitation of "*passing through the thoracic wall and lung of a patient...*and another of the branches *passing through a bronchus of a patient.*" Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Jacobs by adding a second conduit with multiple branches because it is well known in the art, as taught by DeLuccia, deceased et al., to use multiple branches in a conduit in order to establish fluid communication between multiple locations within the body of a patient.

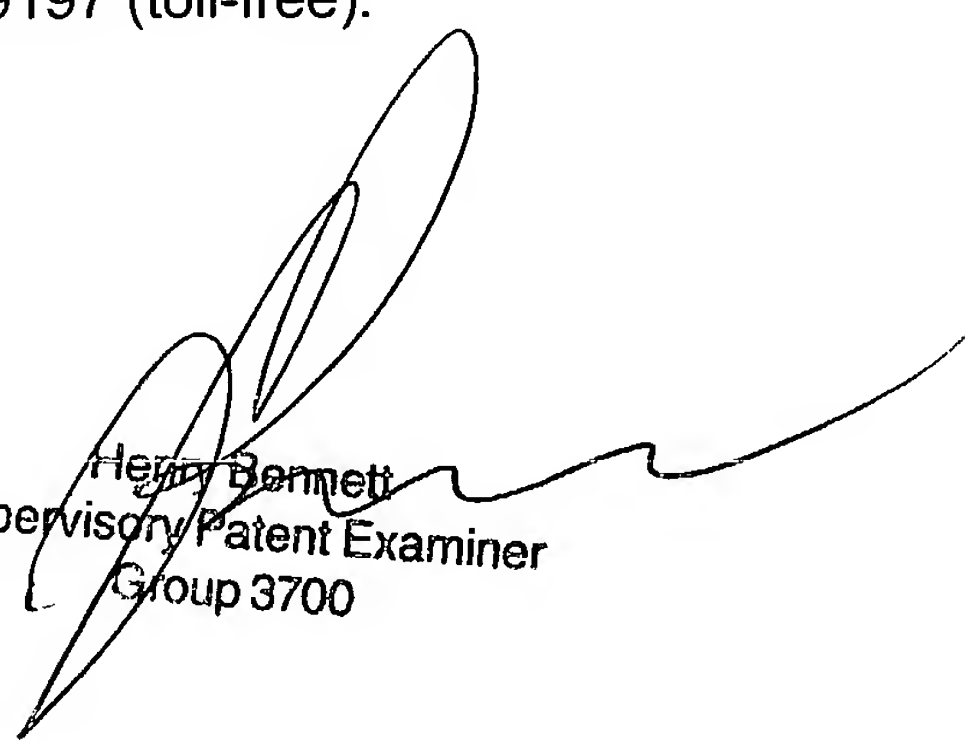
Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **703-306-4055**. The examiner can normally be reached on Monday through Thursday from 8 am until 4 pm ET.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR



Henry A. Bennett
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Group 3700